



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/663,265
		Filing Date	September 16, 2003
		First Named Inventor	Edith Mathiowitz
		Group Art Unit	1633
		Examiner Name	Maria Gomez Leavitt
Sheet 1 of 6	Attorney Docket Number	BU MAT1993-04DIV3CON2	

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		Number	Kind Code <sup>2</sup> (if known)				
ML		4,272,398		Jaffe	06-09-1981		
↓		4,775,624		Bang, et al.	10-04-1988		
		4,861,627		Mathiowitz, et al.	08-29-1989		
		4,863,735		Kohn, et al.	09-05-1989		
		4,897,355		Eppstein, et al.	01-30-1990		
		4,898,734		Mathiowitz, et al.	02-06-1990		
		5,100,669		Hyon, et al.	03-31-1992		
		5,100,792		Sanford, et al.	03-31-1992		
		5,171,217		March, et al.	12-15-1992		
		5,271,961		Mathiowitz, et al.	12-21-1992		
		5,366,881		Singh, et al.	11-22-1994		
		5,639,473		Grinstaff, et al.	06-17-1997		
		5,643,578		Robinson, et al.	07-01-1997		
		5,674,192		Sahatjian, et al.	10-07-1997		
	↓		5,763,416		Banadio, et al.	06-09-1998	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Office. <sup>4</sup>	Number <sup>5</sup>	Kind Code <sup>6</sup> (if known)				
		EP	0-248-531		Southern Research Institute	12-09-1987	.	
		EP	0-330-180		Biomaterials Universe, Inc.	08-30-1989		
		EP	0-302-582		Southern Research Institute	02-08-1989		
		EP	5-79347		Ferring Arzneimittel, GMBH	01-19-1994		
		PCT	WO-93/0886		Massachusetts Institute of Technology	05-12-1993		

Examiner's Signature	Maria Leavitt	Date Considered	03-20-06
----------------------	---------------	-----------------	----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	10/663,265
				Filing Date	September 16, 2003
				First Named Inventor	Edith Mathiowitz
				Group Art Unit	1633
				Examiner Name	Maria Gomez Leavitt
Sheet	2	of	6	Attorney Docket Number	BU MAT1993-04fDIV3CON2

[illegible]

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
		Office. <sup>2</sup>	Number <sup>3</sup>	Kind Code <sup>5</sup> (if known)				
		PCT	WO 93/21906		Brown University Research Foundation	11-11-1993		
		PCT	WO 93/25221		Alkermes Controlled Therapeutics	12-23-1993		
ML		PCT	WO 94/23699		Medisorb Technologies International LP	10-27-1994		
		PCT	WO 94/23738		Medisorb Technologies International LP	10-27-1994		

Examiner's Signature	<i>Marie Leavitt</i>	Date Considered	03-20-06
----------------------	----------------------	-----------------	----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/663,265
		Filing Date	September 16, 2003
		First Named Inventor	Edith Mathlowitz
		Group Art Unit	1633
		Examiner Name	Maria Gomez Leavitt
		Attorney Docket Number	BU MAT1993-04/DIV3CON2
Sheet	3	of	6

OTHER ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		ACSADI, et al., "Human dystrophin expression in mdx mice after intramuscular injection of DNA constructs", <i>Nature</i> , 352(6338):815-8 (1991).	
		BENITA, et al., "Characterization of drug-loaded poly(d, l-lactide) microspheres", <i>J Pharm Sci</i> , 73(12):1721-4 (1984).	
		BLAU, "Muscular dystrophy: Muscling in on gene therapy", <i>Nature</i> , 364(6430):673-5 (1993).	
		CHANGBEN and SHOUYUAN, "Use of human erythrocyte ghosts for transfer of 125I-BSA and 125I-DNA into animal cells through cell fusion", <i>Scientia Sinica</i> , XXV(8):860-865 (1982).	
		COGHLAN, et al., "Gene dream fades away" <i>New Sci.</i> , 148(2005):14-5 (1995).	
		COHEN, "Naked DNA points way to vaccines", <i>Science</i> , 259(5102):1691-2 (1993).	
		CLARK, "Overview and general considerations of wound repair", in <i>The Molecular and Cellular Biology of Wound Repair</i> eds. R Clark and P Henson, pp 3-33 1988.	
		CRYSTAL, "Transfer of genes to humans: early lessons and obstacles to success" <i>Science</i> , 270(5235):404-10 (1995).	
		DAGANI, "Gene therapy advance, anti-HIV antibodies work inside cell", <i>Chemical &amp; Engineering News</i> , pp 3-4 (1993).	
		DUNCAN, "Drug-polymer conjugates: potential for improved chemotherapy", <i>Anticancer Drugs</i> , 3(3):175-210 (1992).	
		EISENBERG and CROTHERS, (eds) "Physical Chemistry with Application to the Life Sciences", Benjamin/Cummings Publishing CO., Menlo Park, CA, p705, 1979.	

Examiner's Signature	Maria Leavitt	Date Considered	03-20-06
----------------------	---------------	-----------------	----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO		Complete If Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/663,265
		Filing Date	September 16, 2003
		First Named Inventor	Edith Mathiowitz
		Group Art Unit	1633
		Examiner Name	Maria Gomez Leavitt
		Attorney Docket Number	BU MAT1993-04DIV3CON2
Sheet	4	of	6

OTHER ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		EISENBRAUN, et al., "Examination of parameters affecting the elicitation of humoral immune responses by particle bombardment-mediated genetic immunization", <i>DNA Cell Biol.</i> , 12(9):791-7 (1993).	
		FYNAN, et al., "DNA vaccines: protective immunizations by parenteral, mucosal, and gene-gun inoculations" <i>Proc Natl Acad Sci U S A.</i> , 90(24):11478-82 (1993).	
		HAWLEY-NELSON, et al., "Lipofectamine reagent: A new higher efficiency polycationic liposome transfection reagent", <i>Focus</i> , 15:73-8 (1993).	
		HENSLY, et al. (eds) "Stedman's Medical Dictionary", 26 <sup>th</sup> edition, Williams and Wilkins, Baltimore, MD. P 1473, 1990.	
		JIAO, et al., "Persistence of plasmid DNA and expression in rat brain cells in vivo", <i>Exp Neurol</i> , 115(3):400-13 (1992).	
		KAY, et al., "In vivo gene therapy of hemophilia B: sustained partial correction in factor IX-deficient dogs", <i>Science</i> , 262(5130):117-9 (1993).	
		LEDLEY, "Nonviral gene therapy: the promise of genes as pharmaceutical products", <i>Hum Gene Ther.</i> , 6(9):1129-44 (1995).	
		LIM, et al., "Microencapsulation of living cells and tissues", <i>J Pharm Sci.</i> , 70(4):351-4 (1981).	
		MARX, "A first step toward gene therapy for hemophilia B?", <i>Science</i> , 262(5130):29-30 (1993).	
		MATHIOWITZ, et al., "Polyanhydride microspheres. IV. Morphology and characterization of systems made by spray drying", <i>J. Appl Polymer Sci.</i> , 45:125-34 (1992).	
		MATHIOWITZ, et al., "Morphology of polyanhydride microsphere delivery systems", <i>Scanning Microsc.</i> , 4(2):329-40 (1990).	

Examiner's Signature	<i>Maria Gomez Leavitt</i>	Date Considered	03-20-06
----------------------	----------------------------	-----------------	----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/663,265
		Filing Date	September 16, 2003
		First Named Inventor	Edith Mathiowitz
		Group Art Unit	1633
		Examiner Name	Maria Gomez Leavitt
Sheet 5 of 6	Attorney Docket Number	BU MAT1993-04DIV3CON2	

OTHER ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		MATHIOWITZ, et al., "Polyanhydride microspheres II. Microencapsulation by solvent removal", <i>J. Appl Polymer Sci.</i> , 35:755- (1988).	
		MATHIOWITZ, et al., "Polyanhydride microspheres I. Hot-melt microencapsulation", <i>J. Controlled Release</i> , 5:13-22 (1987).	
		MATHIOWITZ, et al., "Novel Microcapsules for delivery systems", <i>Reactive Polymers</i> , 6:275-83 (1987).	
		MULLIGAN, "The basic science of gene therapy", <i>Science</i> , 260(5110):926-32 (1993).	
		NABEL, et al., "Direct gene transfer with DNA-liposome complexes in melanoma: expression, biologic activity, and lack of toxicity in humans", <i>Proc Natl Acad Sci U S A.</i> , 90(23):11307-11 (1993).	
		NICOLAU, et al., "In vivo expression of rat insulin after intravenous administration of the liposome-entrapped gene for rat insulin I", <i>Proc Natl Acad Sci U S A.</i> , 80(4):1068-72 (1983).	
		PARTRIDGE, "Gene therapy. Muscle transfection made easy" <i>Nature</i> , (6338):757-8 (1991).	
		ROSENBERG, et al., "Use of tumor-infiltrating lymphocytes and interleukin-2 in the immunotherapy of patients with metastatic melanoma. A preliminary report", <i>N Engl J Med.</i> , 319(25):1676-80 (1988).	
		SALIB, et al., "Utilization of sodium alginate in drug microencapsulation", <i>Pharmazeutisch Industrie</i> , 40(11A):1230-34 (1978).	
		SAWHNEY, et al., "Bioerodible hydrogels based on photopolymerized poly(ethyleneglycol)-co-poly(α-hydroxy acid) diacrylate macromers", <i>Macromolecules</i> , 26:581-7 (1993).	
		TAI, et al., "Microencapsulation of recombinant cells: a new delivery system for gene therapy", <i>FASEB J.</i> , 7(11):1061-9 (1993).	

Examiner's Signature	<i>Maria Gomez Leavitt</i>	Date Considered	03-20-06
----------------------	----------------------------	-----------------	----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO		Complete if Known			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/663,265		
		Filing Date	September 16, 2003		
		First Named Inventor	Edith Mathiowitz		
		Group Art Unit	1633		
		Examiner Name	Maria Gomez Leavitt		
Sheet	6	of	6	Attorney Docket Number	BU MAT1993-04fDIV3CON2

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		ULMER, et al. "Heterologous protection against influenza by injection of DNA encoding a viral protein", <i>Science</i> , 259(5102):1745-9 (1993).	
		VERMA and SOMIA, "Gene therapy — promises, problems and prospects" <i>Nature</i> , 389(6648):239-42 (1997).	
		WILSON, "Cystic fibrosis. Vehicles for gene therapy" <i>Nature</i> , 365(6448):681-2 (1993).	
		WIVEL, et al., "Germ-line gene modification and disease prevention: some medical and ethical perspectives", <i>Science</i> , 262(5133):533-8 (1993).	
		WOLFF, et al. "Direct gene transfer into mouse muscle <i>in vivo</i> " <i>Science</i> , 247(4949 Pt 1):1465-8 (1990).	
		YANG, "Gene transfer into mammalian somatic cells <i>in vivo</i> ", <i>Critical Reviews in Biotechnology</i> , 12(4):335-356 (1992).	

Examiner's Signature	Maria Gomez Leavitt	Date Considered	03-20-06
----------------------	---------------------	-----------------	----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commissioner for Patent, Washington, DC 20231.